AMENDMENT TO RULES

COMMITTEE PRINT 118–36

OFFERED BY MR. WENSTRUP OF OHIO

At the end of subtitle B of title VII, insert the following new section:

SEC. 8___. REQUIREMENT TO PROCURE DOMESTICALLY PRODUCED GENERIC DRUGS.

(a) IN GENERAL.—Subchapter II of chapter 385 of title 10, United States Code, is amended by adding at the end the following new section:

"§ 4865. Procurement of domestically produced generic drugs

''(a) REQUIREMENT.—Subject to subsection (b), the Secretary of Defense may not enter into a contract for the procurement of generic drugs unless the generic drugs—

''(1) are manufactured in the United States; and

''(2) use active pharmaceutical ingredients and key starting materials sourced from—

''(A) the United States; or

''(B) a foreign country or instrumentality designated under subsection (b) of section 301

of the Trade Agreements Act of 1979 (19 U.S.C. 2511) for purposes of the waiver authority under subsection (a) of that section.

''(b) EXCEPTION.—(1) The Secretary may waive the requirement under subsection (a) if the Secretary determines that satisfactory quality and sufficient quantity of a generic drug described in such subsection cannot be procured as and when needed at United States market prices.

''(2) The Secretary of Defense shall submit to the congressional defense committees a written notice of each waiver under this subsection not later than 15 days after granting such waiver.

''(c) DISCLOSURE REQUIREMENT.—The Secretary shall require an offeror for a contract described in subsection (a) to disclose the country of origin of the active pharmaceutical ingredients and key starting materials for the generic drugs that are the subject of such contract.

''(d) DEFINITIONS.—In this section:

''(1) The term 'active pharmaceutical ingredient' has the meaning given such term in section 744A(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-41).

''(2) The term 'generic drug' means a drug—

"(A) approved under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

"(B) licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

"(3) The term 'key starting material' means a raw material, an intermediate, or an active pharmaceutical ingredient that is used in the production of an active pharmaceutical ingredient and that is incorporated as a significant structural fragment into the structure of the active pharmaceutical ingredient.".

(b) APPLICABILITY.—This section and the amendments made by this section shall apply with respect to contracts entered into on or after the date of the enactment of this section.

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